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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/226,895 01/07/99 ROSENBLUM

M D6205

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HM12/0522

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/22/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/226,895	Applicant(s) Rosenblum et al
Examiner Karen Canella	Art Unit 1642



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

4)  Claim(s) 5-11 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 5-11 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19)  Notice of Informal Patent Application (PTO-152)

20)  Other: \_\_\_\_\_

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***Response to Arguments***

1. Claims 5-11 are pending and under consideration.

***Claim Rejections Maintained***

2. The rejection of claims 1, 7-9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Mehta et al (Proceedings of the American Association for Cancer Research, 1997, Vol. 38, p. 88) in view of Flavell et al (Cancer Research, 1997, Vol. 57, pp. 4824-4829) is maintained for reasons of record. Applicant argues that the method of Flavell et al comprising the administration of the anti-CD38-saporin as the sole immunotoxin was relatively ineffective and only when animals were treated with a triple combination of immunotoxins including the anti-CD38-saporin was survival enhanced. Applicant further argues that the targeting of multiple cellular markers enables the immunotoxins to reach the cells which fail to express one or more of the target molecules. This has been considered but not found persuasive. Mehta overcomes the deficiencies of Flavell by teaching the upregulation of the CD38 receptor on cells which fail to express a high density of CD38 receptor by the administration of retinoids, thus allowing for the effective use of anti-CD38-saporin as a single immunotoxin.

3. Claims 1, 5-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al, 1997 and Flavell et al as applied to claims 1, 7-9 and 11 above, and further in view of Mehta et al (Proceeding of the American society for Cancer Research, 1994, Vol. 35, p. 92). Applicant argues that the rejection over Mehta et al (Proceedings of the American Association for Cancer Research, 1997, Vol. 38, p. 88) in view of Flavell et al (Cancer Research, 1997, Vol. 57, pp. 4824-4829) as applied to claims 1, 7-9 and 11 was in error, therefore, the further rejection of claims 5 and 6 in view of Mehta et al (Proceeding of the American society for Cancer Research, 1994, Vol. 35, p. 92) should be withdrawn. This is not found persuasive for the reasons stated *supra*.

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***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 20, 2001